

Amendment and Response  
Applicants: Rudy Mazzocchi et al.  
Serial No.: 10/051,492

Attorney Docket: MVA1001USC3

### REMARKS

This is responsive to the outstanding Office Action issued November 17, 2004. Claims 1 to 63 are pending. Claims 31 to 49, 53 to 57 and 60 to 63 are withdrawn from examination as non-elected. Claims 1, 3 to 6, 12, 14, 17 to 19, 23, 25, 28 to 30, 50 to 52, 58, and 59 are amended. Claims 2 to 11, 13 to 22, 24 to 30, 58 and 59 are original. No claims are canceled.

Applicants wish to thank Examiner Vy Q. Bui for the courtesy of a personal interview regarding this application held on February 3, 2005. At the interview a demonstration of the use of a guidewire and a balloon catheter to track over the guidewire was performed by Richard Kusleika, a representative of ev3 Inc. the assignee of the present invention. At the interview the differences between the claimed invention and the prior art were discussed and are set forth below.

### Rejection Under 35 U.S.C. § 112

Claims 1, 12, 23, 50, 51 and 52 are rejected under 35 U.S.C. § 112, paragraph two as providing insufficient antecedent basis for the limitation "the restraint" applicants have amended these claims to remove the word "the" before the word "restraint". With the above amendments to these claims, all of the claims comply with all requirements of 35 U.S.C. § 112 and this rejection should be withdrawn.

### Drawings

The Examiner is requested to indicate that the drawings have been accepted and approved in the next Office Action, or to indicate specifically any corrections necessary.

### Rejection Under 35 U.S.C. § 102

Claims 1, 2, 4 to 11, 50, 51 and 59 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 4,723,549 to Wholey, et al. ("Wholey"). Although this rejection is predicated under 35 U.S.C. § 102(e), it appears that the appropriate ground of rejection would be 35 U.S.C. § 102(b), based on the effective filing date to which the

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present application is entitled (July 8, 1994) and the date of issue of Wholey (February 9, 1988). Applicants traverse this rejection. It is elementary that a sustainable rejection under 35 U.S.C. § 102(e) or 35 U.S.C. § 102(b) requires the presence in a single reference of all elements recited in the rejected claim.

Claim 1, 50 and 51 require "the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained" and "removing restraint on the filter element to cause the filter element to expand to its expanded configuration." The Wholey filter element 19 does not expand to an expanded configuration when the filter element 19 is unrestrained. Rather, the plurality of ribs 21 of the Wholey filter element 19 expand by inflation of the toroidal filter balloon 29. When the Wholey filter element 19 is unrestrained, "[t]he resilient ribs 21 are prestressed or preformed such that they are biased inward against the catheter" 29 (col. 3, lines 24 to 26) and "[t]he resiliency or compliance of the ribs 21 causes them to retract to the stowed position shown in FIG. 1 when the filter balloon 29 is deflated" (col. 3, lines 51 to 54). To further clarify this difference claim 1 has been amended to describe the filter element as being "radially self-expandable". Claims 2 and 4 to 11, dependent on claim 1, add further elements that patentably define over Wholey. For example, claim 8 requires that "the filter element is mounted on the distal region of the guidewire". In Wholey the filter device 19 is mounted on a distal region of a balloon catheter 1 and not on guidewire 9.

Claims 50, 51 and 59 are not anticipated by Wholey for additional reasons. Each of these claims recites "a filter device including a filter element and means for carrying the filter element". Claims 50 and 51 further recite "advancing the balloon catheter through the vessel over the carrying means until the balloon is positioned at the treatment site". Claim 59 recites "advancing the carrying means through the lumen of the balloon catheter until the filter element is positioned at a desired location distal to the site of stenosis". In Wholey, filter element 19 is carried by balloon catheter 1 and not by guidewire 9. Therefore Wholey can not anticipate claims 50 and 51 because the balloon

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catheter can not be advanced over itself and can not anticipate claim 59 because the balloon catheter can not be advanced through its own lumen.

Accordingly, this rejection of claims 1, 2, 4 to 11, 50, 51 and 59 is unsupportable and must be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 3, 12 to 30, 52 and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wholey. In making this rejection the examiner states that Wholey discloses "substantially all limitations and inherently all steps of using the device as recited in the claims, except for the filter is mounted on the guidewire and the filter is self-expanding" and concludes that it would be obvious to modify the device disclosed in Wholey in a manner recited in the claims. Applicants respectfully disagree and traverse this rejection.

Wholey discloses a device having a structure and use which is significantly different from the invention recited in these claims. Specifically, the device is a balloon catheter which has a filter affixed to the catheter between the distal end 7 and the dilating balloon 13 (Col. 3, lines 7 and 8). The catheter carrying both the balloon and the filter is then advanced or retracted over a guidewire 9. In contrast, claims 3 (which depends from claim 1), 12, 23 and 58 of the present invention each require "a filter element mounted on the guidewire". This is significantly different in both structure and use from the device disclosed in Wholey. Claims 52 and 59 require "means for carrying the filter element". In claim 52 the balloon catheter is advanced "through the vessel over the carrying means". In claim 59 the carrying means is advanced "through the lumen of the balloon catheter until the filter element is positioned at a desired location distal to the site of stenosis". It would not be obvious to modify Wholey to meet the limitations, of these claims. Specifically, Wholey contains no disclosure or teaching which would motivate a person of skill in the art to place the filter element anywhere but on the balloon catheter.

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As a matter of fact, Wholey specifically teaches away from such a modification. For example, Wholey states:

It is a primary purpose of the present invention to provide a catheter for dilating an occluded or stenotic blood vessel which includes, in addition to a dilating balloon, a filter device for trapping embolic fragments of the stenosis dislodged by dilation.

(Col. 1, lines 32 to 37).

Therefore, the rejection of claims 3, 12, 23, 52, 58 and 59 obvious over Wholey should be withdrawn. Dependant claims 13 to 22 and 24 to 30 which depend from claims 12 and 23 respectfully add further limitations in accordance with the previous discussion and are also allowable over Wholey.

Additionally, these claims are not obvious for other reasons. The remarks concerning Wholey in the previous rejection are repeated here as equally pertinent. Claims 12, 23 and 52 require "the filter element being expandable from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained." The Wholey filter element 19 does not expand to an expanded configuration when the filter element 19 is unrestrained. Rather, inflation of the toroidal filter balloon 29 expands the plurality of ribs 21 of the Wholey filter element 19. When the Wholey filter element 19 is unrestrained, "[t]he resilient ribs 21 are prestressed or preformed such that they are biased inward against the catheter" 29 (col. 3, lines 24 to 26) and "[t]resiliency or compliance of the ribs 21 causes them to retract to the stowed position shown in FIG. 1 when the filter balloon 29 is deflated" (col. 3, lines 51 to 54).

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### CONCLUSION

In view of Applicants' present amendments to the claims and the remarks above, all of the claims are submitted to be in condition for allowance.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 2/14/05

By



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